Attorney's Docket No. 702.112.1 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/678,701	Confirmation No.: 9858
Applicant(s):	Keith B. Raskin et al.	
Filed:	October 3, 2003	
Art Unit:	3733	
Examiner:	Anuradha Ramana	
Title:	Radial Ported Needle For Delivering Bone Graft Material and Method of Use	

Docket No.: 702.112.1
Customer No.: 37902

FILED ELECTRONICALLY
Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SECOND AMENDED APPEAL BRIEF UNDER 37 CFR § 41.37

This Second Amended Appeal Brief is filed pursuant to the September 8, 2006 Notice of Appeal to the Board of Patent Appeals and Interferences and to the April 26, 2007 second Notification of Non-Compliant Appeal Brief.

1. *Real Party in Interest*

The real party in interest in this appeal is Wright Medical Technology, Inc., the assignee of the above-referenced patent application.

2. *Related Appeals and Interferences*

There are no related appeals or interferences involving this application or its claimed subject matter.

3. *Status of Claims*

Claims 3-18 are pending. Claims 1-2 are cancelled. No other claims are pending. All claims stand rejected as unpatentable over a combination of prior art references as set forth in greater detail below. The prior art rejection of all pending claims is appealed herein.

4. ***Status of Amendments***

The claims presented on appeal were last amended on November 28, 2005 in response to a first office action. All amendments have been entered.

5. ***Summary of Claimed Subject Matter***

The invention is a method of delivering bone graft paste material to a bone defect area in a patient's body through a minimally invasive portal. In the embodiment of **Claim 3**, the invention includes providing an instrument assembly **10** for delivering the bone graft material to the bone defect area (Specification, p. 5, lines 10-13). The instrument assembly **10** includes a bone graft needle **12** comprising an elongate tubular delivery member **16** having a lumen between a proximal end and a distal end **20** (Specification, p. 5, lines 16-18; Figure 1), and a plurality of ports **36** communicating with the lumen (Specification, p. 7, lines 17-21; Figure 3). The ports **36** are positioned adjacent to the distal end **20** (Specification, p. 7, lines 17-18; Figure 1). An elongate penetrating member **14** is provided for receipt within the bone graft needle **12** (Figures 1-2). The elongate penetrating member **14** is inserted into the lumen of the bone graft needle **12** until a distal end **30** of the elongate penetrating member **14** extends from the distal end **20** of the bone graft needle **12** (Specification, p. 6, lines 19-23; p. 9, lines 13-15; Figures 1-2). The instrument assembly **10** is then inserted through the minimally invasive portal until the open distal end **20** of the bone graft needle **12** operatively reaches the bone defect area **44** (Specification, p. 3, line 21-p.4, line 3; p. 6, lines 13-15; Figure 2), while maintaining the proximal end of the bone graft needle **12** outside of the patient's body (Specification, p. 10, lines 5-7). The elongate penetrating member **14** is removed from the bone graft needle **12** while retaining the distal end **20** of the bone graft needle **12** at the bone defect area **44**. A paste of bone graft material comprising calcium sulfate is formed. (Specification, p. 9, line 21-p. 10, line 3). A syringe is used to deliver the bone graft material to the bone defect area **44** by injecting the paste of bone graft material through the plurality of ports and the distal end of the bone graft needle. (Specification, p. 9, lines 4-9; p. 10, lines 7-20; Figure 2).

Claims 4-10 depend directly from **Claim 3**. In dependent **Claim 4**, the bone graft material further comprises demineralized bone matrix. In dependent **Claim 5**, the bone graft needle has four ports. In dependent **Claim 6,** the ports are equally spaced about a longitudinal axis of the bone graft needle. The equally spaced portals provide an even and balanced distribution of bone graft material to the bone defect area. In dependent **Claim 7**, the ports are variably spaced about a longitudinal axis of the bone graft needle. In dependent **Claim 8**, each port is circular. In dependent **Claim 9**, each the port is elongated in a direction substantially parallel to a longitudinal axis of the bone graft needle.

In dependent **Claim 10**, a distal edge of each port is positioned at a substantially equal distance from a proximal most edge of the distal end of the bone graft needle. **Claims 11-13** depend directly or indirectly from **Claim 10**. In dependent **Claim 11**, the distance from the proximal most edge is between about 0.020 inch to about 0.275 inch. In dependent **Claim 12**, the distance is from the proximal most edge is between about 0.082 inch to about 0.112 inch. In dependent **Claim 13**, each port has a diameter of about 0.063 inch and the distance from the proximal most edge is between about 0.0505 inch to about 0.0805 inch.

Claims 14-18 depend from **Claim 3**. In **Claim 14**, the bone graft needle has an external diameter of about 0.185 inch. The ports have a diameter of about 0.063 inch and are equally spaced about a central longitudinal axis of the bone graft needle. A center of each port is located between about 0.082 inch and about 0.112 inch proximally of a proximal most edge of the distal end of the bone graft needle. In **Claim 15**, the bone graft needle has an external diameter of about 0.115 inch. The ports have a diameter of about 0.047 inch and are equally spaced about a central longitudinal axis of the bone graft needle. A center of each port is located between about 0.0882 inch and about 0.112 inch proximally of a proximal most edge of the distal end of the bone graft needle.

In dependent **Claim 16**, the bone graft needle is made of a 304 series stainless steel, is about 4 inches in length, and has a J-type cannulated distal end. In dependent **Claim 17**, the needle is a 6 cm needle made of a 304 series stainless steel, is about 6 cm in length, and has a J-type cannulated distal end.

The method of dependent **Claim 18** specifies that the bone graft needle is substantially blocked by abutment with bone or other anatomical tissue, yet plugging or clogging of the bone graft needle is avoided because the bone graft material discharges through the ports.

6. ***Grounds of Rejection to be Reviewed on Appeal***

Claims 3-18 are rejected under 35 USC 103(a) as being unpatentable over Reiley et al. (US Patent 6,575,919) in view of Sorenson et al. (US2002/0123723) and further in view of Kerr et al. (US2003/0036762).

7. ***Argument***

Each argument against the prior art rejection of record is set forth below.

Issue 1: **Whether Claims 3-18 are patentable over Reiley et al. (U.S. 6,575,919) in view of Sorenson et al. (US2002/0123723) and further in view of Kerr et al. (U.S. 2003/0036762)**

Claims 3-18 are rejected under 35 USC 103(a) as being unpatentable over Reiley et al. (U.S. 6,575,919) in view of Sorenson et al. (US2002/0123723) and further in view of Kerr et al. (U.S. 2003/0036762). Applicant elected to take this appeal because there is a genuine disagreement between the Examiner and applicant as to whether the three cited references provide the required suggestion or motivation to combine the references to arrive at the claimed invention. Applicant is of the view that a prima facie showing of obviousness has not been established, and that applicant's disclosure is being used as a blueprint to recreate the claimed invention through hindsight reconstruction.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim elements. The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991).

In the Advisory Action, the Examiner took the position that a motivation to combine the three cited references is set forth in the final rejection mailed June 8, 2006. The only passage of the June 8, 2006 office action that might be construed as providing a motivation to combine appears at page 3 of the office action, as follows:

> Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plurality of ports on the tubular delivery member utilized in the method of Reiley et al., as taught by Sorensen et al., to uniformly distribute a volume of treatment fluid to a larger area. Further, it would have been obvious to have utilized a calcium sulfate material, as taught by Kerr et al., in the method of the combination of Reiley et al. and Sorensen et al., since it was well known to utilize this material as a bone filler.

The foregoing passage appears directly after the Examiner's recitation of the teachings of Reiley, Sorenson and Kerr. However, nowhere in the foregoing passage or anywhere else does the Examiner attempt to identify how Reiley, Sorensen, or Kerr suggests or motivates injecting a paste of bone graft material through radial ports located at the distal end of an injection needle.

It is respectfully submitted that the requisite suggestion to combine is found in applicant's disclosure, rather than in the cited references themselves. As discussed in the background section of applicant's specification, the injection of pastes of bone graft materials through needles having an axial port on the distal end is known in the art. Indeed, applicant is a leading manufacturer and supplier of bone graft pastes and syringes for the delivery thereof. Applicant's invention is directed to solving the following problems with prior art delivery methods:

> Since the only opening for delivery of the bone graft material is the axial port, the prior art needle has the disadvantages of: (1) being unable to deliver bone graft material when the axial port abuts bone or other tissues, (2) not being able to radially inject bone graft material, and (3) requiring undesireable excessive force to eject bone graft material through the axial port.

(¶6 of applicant's published application). As set forth in independent **Claim 3**, applicant proposed to solve the problems of the prior art by using an injection needle having both a distal axial port and a plurality of radial ports adjacent the distal end of the needle.

As far as applicant can determine, the cited references do not address the foregoing problems, much less suggest or motivate solutions to these problems. Conspicuously missing from the cited references is any suggestion, teaching or motivation to use a needle having radial ports adjacent a distal end to deliver a paste of bone graft material.

Of the three cited references, only the Sorensen reference teaches the use of a needle having radial ports. However, Sorensen is concerned with solving a different problem than that of the present invention, namely improving the diffusion of medicinal fluids into body tissue. (Sorenson, ¶¶3-4). Reflecting the different objective of the Sorenson patent, Sorenson depicts a needle having a plurality of radial ports **85** that are positioned all along the length of the needle, as shown in Sorenson **Figure 1**, below:

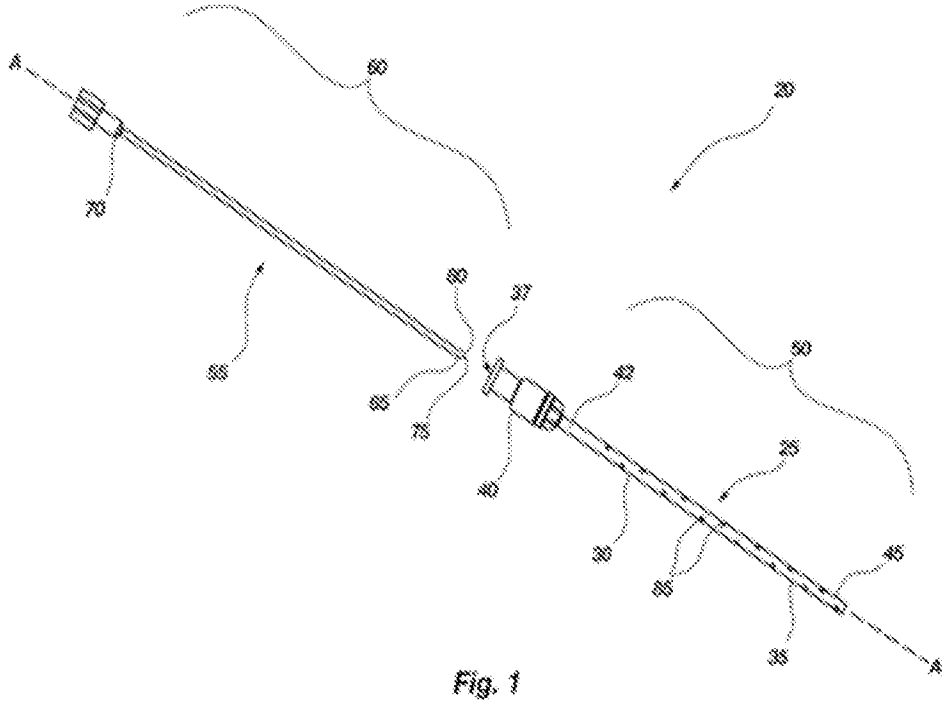

Fig. 1

According to Sorenson, the arrangement of the radial ports **85** "more uniformly disperses medication to a treatment zone inside a patient, compared to point-source fluid introduction." (Sorenson, ¶33). Sorenson further states: "The treatment zone for fluids injected through the instant invention may be characterized as being cylindrical, compared to the spherical treatment zone of a point source device, such as a needle orifice." (Sorenson, ¶33).

Nothing in Sorenson suggests providing the plurality of radial ports adjacent the distal end of the needle, and such an arrangement would appear to render Raskin's needle ineffective for its intended purpose of uniformly dispersing medication into a cylindrical treatment zone. As such, Sorenson teaches away from the claimed invention. Likewise, nothing in Sorensen suggests the use of an axially and radially ported needle to discharge any type of paste material, including particularly bone graft materials.

While Sorenson's needle having a plurality of radial ports may be effective for the uniform dispersion of medicinal fluids, the delivery of calcium sulfate bone graft paste material to a bone defect area presents a much different challenge. Calcium sulfate bone paste is a viscous material that does not diffuse through tissues in the manner of a medicinal fluid. Instead, as specified in applicant's independent **Claim 3**, the bone paste is injected into a bone defect area (e.g. a cavity) in the bone of a patient. The bone paste sets into a hardened mass in the bone defect area. The hardened mass of bone paste remains in the bone defect area until it has been resorbed over time (e.g. about two weeks for calcium sulfate bone pastes) to form bone. Thus, applicant is not interested in achieving uniform diffusion of injected bone paste through tissue, in the manner of Sorenson, but rather in filling a bone defect area, such as a cavity. As noted above, applicant's objective is to improve the delivery of bone graft paste into bone defect areas in situations where injection of bone paste is impeded, such as when the axial port is blocked by bone. It is important to note that applicant's claims are also directed to injecting calcium sulfate bone paste through a "minimally invasive" (i.e. short) portal, which typically presents a situation in which the surgeon cannot see conditions in the bone defect area while injecting the bone graft. By providing the radial ports adjacent the distal end of the needle, the surgeon has a better chance of successfully filling the bone defect area, even if the axial opening on the distal end of the needle is blocked.

The Examiner takes the position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plurality of ports on the tubular delivery member utilized in the method of Reiley et al., as taught by Sorensen et al., to uniformly distribute a volume of treatment fluid to a larger area. However, as noted above, applicant is not interested in uniformly distributing a volume of treatment fluid to a larger area. Importantly,

neither is Reiley. As can be seen in Reiley **Figure 13** (below), Reiley is directed to injecting a paste material **132** into a bone defect through a cannula having a distal axial port:

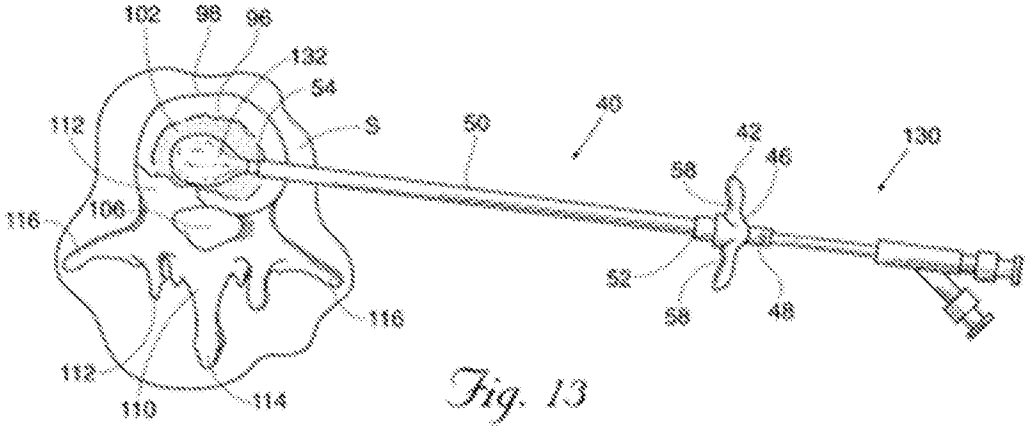

Fig. 13

As can be seen in Reiley **Figure 13**, if Reiley's cannula **50** were provided with a plurality of ports along its length in the manner of Sorenson (see Sorenson **Figure 1**, above), delivery to the bone defect area would be compromised, since the paste would tend to leak through the ports prior to injection through the distal port and into the bone defect. Therefore, it is not clear to applicant where the motivation arises to combine Reiley and Sorenson for use in injecting a paste of bone graft material. In view of the very different nature of Sorenson's medicinal fluids and applicant's paste of bone graft material, applicant is of the view that the references, even when taking into account the knowledge generally available to one of ordinary skill in the art at the time of the invention, would not have suggested applicant's claimed combination. Rather, it is applicant's specification that identifies the source of the problem and its solution.

Of the three cited references, only Kerr mentions the use of calcium sulfate bone paste materials. However, as discussed in applicant's specification, the delivery of calcium sulfate bone graft pastes through syringes is known. Kerr is directed to solving a different problem than that addressed by the present application, namely the delivery of highly viscous materials through an axial port. Kerr used the following passage to describe the problem to which the invention of Kerr is directed:

> However, especially with highly viscous or solid, yet pliable cement compositions, it is often difficult with a standard push-type syringe to generate the

> pressure needed to express the material through the syringe outlet opening by exerting pressure on the syringe plunger in an axial direction. Another serious problem is that once sufficient pressure is applied to the plunger, it is difficult to precisely control the amount of material expelled through the outlet opening of the barrel, resulting in extraosseous (i.e., outside the bony cavity) flow.

(Kerr, ¶[0003]). Kerr's solution to solving the problem is to provide a threaded syringe barrel and plunger combination. As Kerr explains:

> Those skilled in the art will appreciate that significant pressures can be generated within barrel 12 as plunger 16 is advanced into barrel 12 by rotating plunger 16 relative to barrel 12, particularly when highly viscous or solid, yet pliable bone cement compositions are situated within barrel 12. In that regard, in a preferred embodiment the mechanical advantage provided through the use of the threaded plunger is preferably about 5 to 1.

(Kerr, ¶[0038]). Although Kerr describes the configuration of the distal end of the syringe barrel and the axial port, and makes reference to radial aspects of the device, Kerr does not identify the problems raised in applicant's specification, nor suggest their solution. In particular, Kerr does not suggest the use of radial ports on the distal end. Instead, Kerr remains focused on the conventional use of an axial port on the distal end. Therefore, in applicant's view, Kerr does not provide the requisite suggestion or motivation to combine the references in the manner of the claimed invention.

As noted above, conspicuously missing from the cited references is any suggestion, teaching or motivation to use a needle having a radial port to deliver a bone graft material. The present case is analogous in some respects to *In re Dembiczak*, 175 F.3d 994, 50 USPQ.2d 1614 (Fed. Cir. 1999). In *In re Dembiczak*, the claims were drawn to a generally round, orange plastic trash bag with a jack o'lantern face imprinted thereon. The claims were initially rejected as obvious in view of conventional trash bags in combination with a reference showing a jack o'lantern face on an orange paper bag stuffed with newspapers. However, the Federal Circuit reversed, finding that there was no suggestion or motivation to combine the cited references. In establishing the nonobviousness of Dembiczak's invention, the Federal Circuit noted the following concerns about application of the "suggestion to combine" requirement:

> Our analysis begins in the text of section 103 quoted above, with the phrase 'at the time the invention was made.' For it is this phrase that guards against entry into the 'tempting but forbidden zone of hindsight,' see *Loctite*

> *Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 873, 228 U.S.P.Q. (BNA) 90, 98 (Fed. Cir. 1985), overruled on other grounds by *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 46 U.S.P.Q.2D (BNA) 1097 (Fed. Cir. 1998), when analyzing the patentability of claims pursuant to that section. Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See, e.g., *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. (BNA) 303, 313 (Fed. Cir. 1983). *Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one 'to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.' Id.*
>
> Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. . . . Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight.

Id., 175 F.3d at 998-999 (emphasis added); see also MPEP §§ 2142, 2143.01.

In this case, as in *Dembiczak*, the cited references lack the necessary suggestion to combine the references in the manner of the claimed method. This view is reinforced by the fact that the rejection is based on a combination of three rather than two references. In the absence of a suggestion, teaching, or motivation to modify Reiley's method to include Sorenson's radial openings, and in the absence of a suggestion, teaching or motivation to further modify Reiley/Sorenson to use a calcium sulfate bone graft paste according to Kerr, it is respectfully suggested that a *prima facie* case of obviousness has not been established.

For the reasons set forth above, Applicants respectfully request that the Board overturn the rejections of record.

8. *Claims Appendix*

An appendix containing a copy of the claims involved in the appeal is attached below.

9. ***Evidence Appendix***

None.

10. ***Related Proceedings Appendix***

None.

CONCLUSION

In view of the foregoing arguments, Appellant respectfully submits that Claims 3-18 are patentable over the cited references. A decision from the Board of Patent Appeals and Interferences reversing the final rejection of the pending claims is therefore earnestly solicited.

Respectfully submitted,

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CLAIMS APPENDIX

1-2. (Cancelled)

3. (Previously presented) A method of delivering bone graft paste material to a bone defect area in a patient's body through a minimally invasive portal, comprising:

providing an instrument assembly for delivering the bone graft material to the bone defect area, said instrument assembly comprising:

a bone graft needle for delivery of bone graft material to the bone defect area, said needle comprising an elongate tubular delivery member having a lumen between a proximal end and a distal end, said elongate tubular delivery member having a plurality of ports communicating with said lumen, said ports positioned adjacent to said distal end, and

an elongate penetrating member for receipt within said bone graft needle,

inserting said elongate penetrating member into said lumen of said bone graft needle until a distal end of said elongate penetrating member extends from said distal end of said bone graft needle,

inserting said instrument assembly through the minimally invasive portal until said open distal end of said bone graft needle operatively reaches the bone defect area, while maintaining said proximal end of said bone graft needle external of the patient's body,

removing said elongate penetrating member from said bone graft needle while retaining said distal end of said bone graft needle at the bone defect area,

forming a paste of bone graft material, said bone graft material comprising calcium sulfate, and

using a syringe to inject said paste of bone graft material through said plurality of ports and said distal end of said bone graft needle to thereby deliver said bone graft material to the bone defect area.

4. (Previously presented) A method of claim 3, wherein said bone graft material further comprises demineralized bone matrix.

5. (Previously presented) The method of claim 3, wherein said bone graft needle has four ports.

6. (Previously presented) The method of claim 3, wherein said ports are equally spaced about a longitudinal axis of said bone graft needle, to thereby provide an even and balanced distribution of bone graft material to the bone defect area.

7. (Previously presented) The method of claim 3, wherein said ports are variably spaced about a longitudinal axis of said bone graft needle.

8. (Previously presented) The method of claim 3, wherein each said port is circular.

9. (Previously presented) The method of claim 3, wherein each said port is elongated in a direction substantially parallel to a longitudinal axis of said bone graft needle.

10. (Previously presented) The method of claim 3, wherein a distal edge of each said port is positioned at a substantially equal distance from a proximal most edge of said distal end of said bone graft needle.

11. (Previously presented) The method of claim 10, wherein said distance is between about 0.020 inch to about 0.275 inch.

12. (Previously presented) The method of claim 11, wherein said distance is between about 0.082 inch to about 0.112 inch.

13. (Previously presented) The method of claim 11, wherein each said port has a diameter of about 0.063 inch and said distance is between about 0.0505 inch to about 0.0805 inch.

14. (Previously presented) The method of claim 3, wherein said bone graft needle has an external diameter of about 0.185 inch, said ports have a diameter of about 0.063 inch, said ports are equally spaced about a central longitudinal axis of said bone graft needle, and a center of each said port is located between about 0.082 inch and about 0.112 inch proximally of a proximal most edge of said distal end of said bone graft needle.

15. (Previously presented) The method of claim 3, wherein said bone graft needle has an external diameter of about 0.115 inch, said ports have a diameter of about 0.047 inch, said ports are equally spaced about a central longitudinal axis of said bone graft needle, and a center of each said port is located between about 0.0882 inch and about 0.112 inch proximally of a proximal most edge of said distal end of said bone graft needle.

16. (Previously presented) The method of claim 3, wherein said bone graft needle is made of a 304 series stainless steel, is about 4 inches in length, and has a J-type cannulated distal end.

17. (Previously presented) The method of claim 3, wherein said needle is a 6 cm needle made of a 304 series stainless steel, is about 6 cm in length, and has a J-type cannulated distal end.

18. (Previously presented) The method of claim 3, wherein said distal end of said bone graft needle is substantially blocked by abutment with bone or other anatomical tissue, yet plugging or clogging of the bone graft needle is avoided because said bone graft material discharges through said ports.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.